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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,613 ⁷⁵⁹⁰	08/04/2000	Holly Hogrefe	4121.0116-07	6689

7590 07/03/2002
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Palo Alto, CA 94304

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/03/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,613

Applicant(s)

HOGREFE ET AL.

Examiner

Cynthia B Wilder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-44 and 69-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44 and 69-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

1. Applicant's election with traverse of species "dUTPase" in Paper No. 10 is acknowledged. The traversal is on the ground(s) that "in one step of the method comprises adding all of the components subject to the election requirement". Applicant contends that "removing all but one of the enumerated components would preclude claiming an invention wherein all the components were included." Applicant states that "these claims are thus generic".. This is not found persuasive because the claims as written suggest that the method is capable of operating with only one component or species (see claims). The requirement is still deemed proper and is therefore made FINAL.

Sequence listing/CRF

2. Applicant's submission of a CRF and a paper copy of the sequence listing in Paper No.10 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

3.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

4. Claims 40-44 and 69-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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(a) Claims 40-44 and 69-71 and 73 are indefinite as being incomplete in claim 40 and 69 for omitting essential elements; such omission amounting to a gap between the steps. The omitted elements are method steps which indicates how the claimed method operates to enhance a nucleic acid polymerase reaction as disclosed in the specification at the Examples. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well and make clear the subject matter from which other would be precluded. *Ex parte Erlich, 3 USPQ2d 1011 at 6.*

(b) Claims 40-44 are confusing and redundant in claim 40 at step (a) for "mixing a nucleic acid sequence template for a nucleic acid polymerase with at least one nucleic acid polymerase". It is suggested inserting "reaction" after "template for a nucleic acid polymerase" or clarify intent.

(c) Claims 43, 70-74 are indefinite at "PCR", "RT-PCR", "PEF" and "dUTP" because abbreviations often have more than one meaning in the art. It is suggested amending the claims such that the full names of the abbreviations are recited.

(d) Claims 72 and 74 lacks proper antecedent basis in claim 72 at the step of "changing the amount of dUTP present or generated during the reaction.." because there is no prior indication that any dUTP was added or generated in the polymerization reaction. Clarification is required.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

6. Claims 40, 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes.

(Proc. Natl. Acad. Sci. USA, vol. 91, pp 2216-2220, March 1994). Regarding claim 40, Barnes teaches a method for enhancing a nucleic acid polymerase reaction comprising mixing a nucleic acid sequence template for a nucleic acid polymerase reaction with a nucleic acid polymerase and a polymerase enhancing compositions comprising an isolated, purified synthetic protein obtained from bacteria (Abstract and col. 1, lines 14-16 and first paragraph from bottom of col. 1).

Regarding claim 42-44, Barnes teaches a method of claim 40, wherein the reaction is an amplification reaction comprising a polymerase chain reaction (PCR) process and a cycling sequencing process (see section entitled "materials and methods"). Therefore, Barnes meets the limitation of claims 40-44 of the instant invention

7. Claims 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielson et al. (Us 5, 449, 603, Sept 1995). Regarding claim 40, Nielson et al. teach a method for enhancing nucleic acid polymerase reaction comprising mixing a nucleic acid template for a nucleic acid

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polymerase reaction with a nucleic acid polymerase and a polymerase enhancing composition comprising a polymerase-enhancing protein complex of a naturally occurring protein (col. 2, lines 6-9, 52-65 and col. 13, lines 7-41).

Regarding claim 41, Nielson et al. disclose a method of claim 40, wherein the reaction can be a replication reaction (col. 2, lines 6-10 and 23-25).

Regarding claim 42, Nielson et al. teach a method of claim 40, wherein the reaction is an amplification reaction (col. 13, lines 7-41).

Regarding claim 43, Nielson et al. teach a method of claim 40, wherein the reaction is comprises a PCR process.

Regarding claim 44, Nielson et al. disclose a method of claim 43 further comprising in vitro mutagenesis process (col. 2, lines 52-62). Therefore, Nielson et al. meet the limitation of claims 40-44 of the instant invention.

7. Claims 71 and 73 are rejected under 35 U.S.C. 102(a) as being anticipated by Lasken et al. (*JBC*, vol. 271, pp 17692-17696, 1996). Regarding claims 71 and 73, Lasken et al. teach a method of enhancing a nucleic acid polymerase reaction comprising performing the reaction in the presence of a dUTPase activity wherein the dUTPase activity comprises an archael dUTPase (page 17694, col. 2, lines 3-10 and page 17696, col. 1, lines 19--21 and 28-31). Therefore, Lasken et al. meet the limitations of claims 71-73 of the instant invention.

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Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 40-44 and 69-74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,183,997 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of patent '997 disclose an obvious species of the instant invention. Claims 1-29 of patent '997 teach a composition comprising at least one component

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possessing nucleic acid polymerase enhancing activity selected from the group consisting of : an isolated or purified naturally occurring polymerase enhancing protein obtained from an archeabacteria source; a wholly or partially synthetic protein having the same amino acid sequence as said naturally-occurring protein or analogs thereof possessing polymerase enhancing activity. The claims further teach wherein the composition comprises at least one subunit having a molecular weight of approximately 45 kD.

The claims of patent '997 do not expressly teach wherein the composition comprising the polymerase enhancing activity is utilized in a polymerization reaction as claimed in the instant invention , however, one of ordinary skill in the art would recognize that the composition is capable of use in methods of enhancing a nucleic acid polymerase reaction. The claims of the instant invention and patent '997 are not patentably distinct and only differ slightly in scope.

Conclusion

10. No Claims are allowed. However claims 69, 70, 72 and 74 are free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

June 20, 2002


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

6/25/02